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EXAMINER	
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ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,396	SNIEGOWSKI ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *54-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/2/04,7/19/04,8/9/04,1/30/06,3/21/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 7 March 2007 is acknowledged. The traversal is on the ground(s) that the formerly independent claims now recite all the limitations of the sole independent claim 1. With regard to claims 54-60, Applicant's argument is not persuasive because the claimed apparatus does not require any pressure regulating capabilities, and may be used to perform a materially different method than that claimed in claim 54.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's arguments with regard to the examination of claims 1-53, as amended, are persuasive. Claims 54-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7 March 2007.

3. Claims 1-53 are examined herein on the merits.

Information Disclosure Statement

4. The references cited by applicants in the information disclosure statements filed 2 March 2004, 19 July 2004, 9 August 2004, 30 January 2006, and 21 March 2007 have been made of record. Examiner has considered the voluminous references to the best of her ability.

While the statements filed do not comply with the guidelines set forth in MPEP 2004 regarding both the number of references cited and the elimination of clearly irrelevant art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 does not require that the information be material; rather, they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references. However, the cloaking of a clearly relevant reference by inclusion in a long list of citations may not comply with Applicant's duty of disclosure. *See* Penn Yan Boats, Inc. v. Sea Lark boats Inc., 359 F. Supp. 948, *aff'd* 479 F. 2d. 1338.

Applicant is advised that the MPEP states the following with respect to large information disclosure statements:

> *Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more is highly relevant to patentability.* MPEP § 609.04(a)(III).

This statement is in accord with dicta from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), states that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888.

The MPEP provides more support for this position. In a subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

> *It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See* Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F.Supp 948 (S.D. Fla. 1972) *aff'd* 479 F.2d 1338 (5th Cir 1974). *See also* MPEP § 2004.

Therefore, it is recommended that if any information that has been cited by Applicants in the previous disclosure statement is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

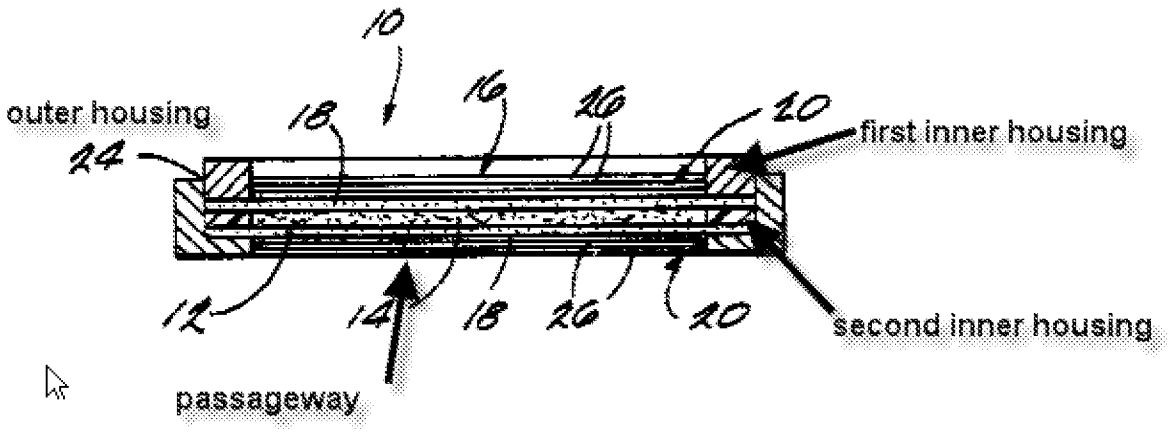
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-7 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,807,406 to Brauker et al.

In the specification and figures, Brauker discloses the apparatus as claimed by Applicant. With regard to claims 1 and 13, Brauker discloses an implantable flow module assembly 10 comprising a first outer housing 24, a second housing (or first inner housing, as labeled by the Examiner below) at least partially disposed within the first housing with a flow path therethrough, and a microfabricated or MEMS flow module or filter element 18 mounted to the second housing such that all flow through the fluid

path travels through the filter element 18 (see FIG 1C as annotated by Examiner, below, and accompanying text).

With regard to claims 2, 4, 5, Brauker teaches that the rings may be made of titanium (see column 12, lines 1-2), which is a rigid material.



With regard to claims 3, 6, and 9, Brauker illustrates that the first housing 24 comprises first and second ends with an opening between them, wherein the cylindrical second housing (or first inner housing, as labeled above), is disposed within the opening, with the filter element recessed within, or disposed within the confines, of the inner housing, at an end of the housing.

With regard to claims 10-12, Brauker discloses that the apparatus may comprise a third housing, or second inner housing, as labeled by the Examiner above, wherein the filter module 18 is sandwiched or bonded in a fixed position between the first and second inner housing between the flow paths created by the housings.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,807,406 to Brauker et al.

In the specification and figures, Brauker discloses the apparatus substantially as claimed by Applicant (see rejection above).

With regard to claim 8, Brauker fails to disclose that the filter module is disposed between the first and second ends of the inner housing. It is the position of the Examiner that the inner housing may comprise both first inner housing and second inner housing as annotated by the Examiner in the FIG above, wherein the filter 18 is disposed between the pieces. As such, Brauker suggests the structure claimed by Applicant, wherein a filter module is disposed between a first and second end of an inner housing.

9. Claims 14-30, 32-49, 52, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,807,406 to Brauker et al in view of US 6,694,998 to Hunnicutt.

In the specification and figures, Brauker discloses the apparatus substantially as claimed by Applicant (see rejection above).

With regard to claims 14, 15, 33, 34, 52, and 53, Brauker fails to disclose the specific structure of the microfabricated or MEMS flow module. Hunnicutt discloses a MEMS flow module or microvalve 7 that is connected to a fluid conduit (see column 5, lines 43-47). The flow module or microvalve 7 comprises a baffle in the form of a slider plate or tuning element 40 in plate 16, which is disposed between outer plates 14, 18 with recesses or ports 106, 109, respectively (see FIG 2A, column 4, lines 28-35, column 6, lines 15-22, column 8, lines 20-40). The baffle or slider element 40 moves in response to pressure changes, creating a change in the relative positions of the baffle 40 and the first plate 14 (see column 6, lines 23-38). The flow rate of fluid exiting the module is dependent on the position of the tuning element, since it creates a barrier to flow in the fluid path, thus changing fluid flow direction and meeting the limitations of the claims. It would have been obvious to one having ordinary skill in the art at the time of invention to place the MEMS flow module as disclosed by Hunnicutt in the housing disclosed by Brauker, since Brauker discloses that such a housing may comprise a microfabricated flow element.

With regard to claims 16, 17, 35, 36, and 43, Hunnicutt illustrates that the valve or baffle 40 is disposed at a particular location relative to plate 14 and is capable of moving along the axis which comprises the direction of flow into the port (see column 8, lines 11-58).

With regard to claims 18, 29, 37, and 48, Hunnicutt discloses a slider element or baffle that comprises spring 44 that connects to the plate elements (see column 6, lines 15-62).

With regard to claims 19 and 38, it has been held that the mere duplication of the essential working parts of an invention found in the prior art is within the skill of a person of ordinary skill in the art. See MPEP § 2144.04. Absent any disclosure that the additional springs claimed by applicant provide a critical or unexpected result, it is the position of the examiner that the additional springs claimed by applicant are the mere duplication, and therefore, obvious modifications of the prior art.

With regard to claims 20, 23, 25, 39, and 41, the limitations amount to a functional recitation of the operation of the claimed device without any limitations that structurally differentiate the claimed device from the device suggested by the prior art. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. See MPEP § 2114. It is the position of the examiner that the device suggested by the prior art is capable of operating in the manner claimed by applicant—that fluid flow through any of the flow ports must proceed around the baffle (thus changing the direction of fluid flow), since the references all teach that fluid flows through flow ports and around the baffle before leaving the device. Accordingly, the instantly claimed device is unpatentable over the prior art.

With regard to claims 21 and 44 as best understood by the Examiner, Hunnicutt discloses that the flat slider or tuning element 40 moves parallel to the flat plate 14, providing a proportional movement across the entire tuning element.

With regard to claims 22, 30, 40, 42, and 49, it has been held that the mere duplication of the essential working parts of an invention found in the prior art is within

the skill of a person of ordinary skill in the art. See MPEP § 2144.04. Absent any disclosure that the additional flow ports and tuning elements claimed by applicant provide a critical or unexpected result, it is the position of the examiner that the plurality of flow ports claimed by applicant are the mere duplication, and therefore, obvious modifications of the prior art.

With regard to claims 24, 26, and 45, applicant claims the action of the fluid flowing through the device. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. See MPEP § 2114. Applicant's claim language does not provide a structural limitation distinguishing it from the prior art of record. As such, the claims read on the disclosures of the prior art.

With regard to claims 27 and 46, and applicant's "means for limiting,", he language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for " or "step for; "

(B) the "means for " or "step for " must be modified by functional language; and

(C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification.

In the specification, applicant defines the "means for limiting" as a overpressure stops, or protrusions. Accordingly, the examiner is interpreting the "means for limiting" to encompass protrusions that affect the movement of the tuning element and its equivalents. Equivalent structures may include those that perform the function specified in the claim, structures that are not excluded by any specific definition provided in the specification for an equivalent, or is a structural equivalent of the corresponding element disclosed in the specification. See MPEP 2183.

With regard to claims 27, 32, and 46, Hunnicutt discloses that the MEMS flow module may comprise protrusions 82, 84, 86 that limit the movement of the slider or tuning element 40 within the housing (See column 7, lines 31-45, FIG 3), thereby meeting the limitations of the claims.

With regard to claims 28 and 47, Hunnicutt discloses that the MEMS microvalve is moved in response to pressure fluctuations and does not disclose the use of any powered actuator, suggesting that the apparatus is a passive device.

10. Claims 31, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,807,406 to Brauker et al in view of US 6,694,998 to Hunnicutt, further in view of US 2002/0107471 to Thompson.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejections above)

With regard to claims 31 and 50, the cited prior art fails to disclose that the plates are connected by an annular support that defines an enclosed space. Brauker discloses

that the microfabricated flow element 18 may be disposed in an annular space enclosed by rings. Hunnicutt discloses the structure of the tuning element and the plates. Thompson discloses an implantable MEMS flow module comprising a MEMS flow restrictor or module 34 within a flow path (see FIG 2). The flow module comprises a flow regulator 48 and moveable valve or tuning element 46 that controls fluid flow between flow paths 38, 36 (see FIGS 6B, 7B). The entire control apparatus is disposed within an enclosed space defined by outer walls (see FIG 7B). All the elements of the claims are known in the art, and one of ordinary skill in the art may have combined the known elements by known methods to yield the predictable results of a MEMS flow module in an annular enclosed housing. Taken together, the references reasonably suggest to one of ordinary skill in the art a MEMS flow module with movable tuning element as disclosed by Hunnicutt in an annular space as disclosed by Brauker, wherein the apparatus is disposed within a closed space, as disclosed by Thompson.

With regard to claim 51, Hunnicutt discloses that the MEMS flow module may comprise protrusions 82, 84, 86 that limit the movement of the slider or tuning element 40 within the housing (See column 7, lines 31-45, FIG 3), thereby meeting the limitations of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
22 April 2008